



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/628,794	07/28/2003	Robert I. Rudko	LE-205J	4536

7590 07/11/2006

Iandiorio & Teska
260 Bear Hill Road
Waltham, MA 02451-1018

EXAMINER

PEFFLEY, MICHAEL F

ART UNIT	PAPER NUMBER
----------	--------------

3739

DATE MAILED: 07/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/628,794

Applicant(s)

RUDKO ET AL.

Examiner

Michael Peffley

Art Unit

3739

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 16-18 is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1-17-06</u> . | 6) <input type="checkbox"/> Other: _____ |

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 5, 2006 has been entered.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

Claims 1-5 and 10-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Jaafar et al (2002/0045848).

As asserted in the previous Office action, Jaafar et al disclose a device comprising a lumen (16) including a steerable tip portion (36) extending from a joint portion (i.e. distal end of sheath 16 after the balloon). A registration means (balloon - 21) holds the joint portion in place and a source of ablative energy (laser - 12) is in communication with the lumen and delivered to the tip portion via an optical fiber (32).

Claims 1-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Edwards et al (5,366,490).

Edwards et al also disclose a device comprising a lumen (14) having a steerable distal tip (i.e. stylet – 36) extending from a joint portion (34). A registration means, including balloons (30,32) hold the joint member in place during movement/treatment with the tip member. The tip member may include various devices, including RF electrodes and laser fiber optics (col. 5, lines 21-24) and is connected to an ablative laser source (see Abstract). The second balloon (30) is deemed to act in concert with the first balloon as a barrier (i.e. tissue is trapped between the two balloons), and the device is deemed to be inherently capable of being used in the manner described in the claims (i.e. in the heart) even though there is no explicit recitation of such a use in the Edwards et al device.

Allowable Subject Matter

Claims 16-18 are allowed.

Response to Arguments

Applicant's arguments with respect to claims 1-15 have been considered but are not persuasive.

Regarding the Jaafar et al reference, applicant contends on pages 2-3 of the response that Jaafar et al fail to disclose a steerable tip portion extending from a joint portion. The examiner disagrees. The examiner has clearly indicated that element 36 is the "steerable tip portion", with element 36 being connected to guidewire 14. Jaafar et al clearly teach that the guidewire 14 is steerable. See, for example, paragraphs [0014], [0026] and claim 1. In as much as the guidewire is steerable, the tip member is also inherently steerable (i.e. steered by the guidewire). Figure 7 depicts the distal tip

member being steered or deflected into a side vessel. The examiner maintains that the term "deflectable" falls within the meaning of a tip that is "steerable".

Concerning the Edwards et al reference, applicant asserts on pages 3 and 4 of the response that Edwards fails to disclose a distal steerable tip portion extending from a joint portion. The examiner disagrees. The stylet distal tip is steerable in that the stylet block controls the direction of the stylet as it is advanced from the device to treat tissue. The examiner maintains that the section where the stylets extend from the catheter (reference area 34) may be considered a "joint", and the distal tips of the stylets are steered or deflected using the stylet block.

Regarding claim 15, applicant asserts that Edwards fails to disclose a balloon on the ventricular side of a valve to support the leaflets of the valve as claimed by the applicants. The examiner agrees that Edwards has no express disclosure of such an intended use of the device, but that the balloons in the Edwards device are inherently capable of performing that function. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Applicant has not demonstrated why the Edwards balloon would be structurally incapable of supporting the leaflets of a valve. The examiner maintains the Edwards catheter may be inserted through the valve such that the distal balloon (30) rests on the back side of the valves just as shown in applicant's Figure 5. Such a use would provide the proximal balloon and the stylets on the proximal side of the valves. That Edwards

does not expressly disclose the use of the device for this purpose does not mean the device is not capable of being used in that manner.

It is noted that applicant has not reasserted any of the arguments made in the previous response of August 19, 2005. In particular, applicant has not argued that Jafaar et al fails to disclose a source of ablation energy or a registration means, and has not argued that Edwards fails to disclose an ablative energy source.

Conclusion

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

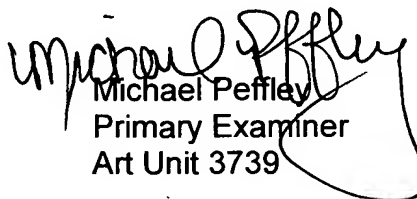
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Art Unit: 3739

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (571) 272-4770. The examiner can normally be reached on Mon-Fri from 6am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Michael Peffley
Primary Examiner
Art Unit 3739

mp
July 5, 2006